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<p>(21) International Application Number: PCT/US97/21303</p> <p>(22) International Filing Date: 20 November 1997 (20.11.97)</p> <p>(30) Priority Data: 08/754,605 20 November 1996 (20.11.96) US</p> <p>(71) Applicant: CROWN LABORATORIES, INC. [US/US]; 6780 Caballo Street, Las Vegas, NV 89119 (US).</p> <p>(72) Inventors: NASH, Scott, Oldham; 678 Cervantes Drive, Henderson, NV 89014 (US). NASH, Craig, Emery; Apartment 234, 230 E. Flamingo Road, Las Vegas, NV 89109 (US). PARK, Peter, S., W.; 1985 Waverly Circle, Henderson, NV 89014 (US).</p> <p>(74) Agent: WALDBAUM, Maxim, H.; Fried, Frank, Harris, Shriver &amp; Jacobson, One New York Plaza, New York, NY 10004 (US).</p>		<p>(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, UZ, VN, YU, ZW, ARIPO patent (GH, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).</p> <p>Published <i>With international search report.</i></p>	
<p>(54) Title: IMPROVED LIQUID NUTRITIONAL SUPPLEMENT AND ASEPTIC PROCESS FOR MAKING SAME</p> <p>(57) Abstract</p> <p>An improved nutritional supplement and aseptic process for making same is provided. The liquid nutritional supplement provides improved concentration of many recommended both macro- and micro-nutrients in a shelf-stable form. A process for making the improved nutritional supplement is also provided, in which the supplement is subjected to higher-pressure homogenization of the supplement after ultra-high temperature turbulent flow sterilization. The improved nutritional supplement of the present invention provides a higher level of nutrients with many recommended minerals and vitamins in a smaller volume than supplements not having the high level of total solids of the liquid nutritional supplement of the present invention. The supplement also has an improved mouth feel, flavor profile and taste, resulting in higher intake of the supplement, especially beneficial for effective nutritional management of consumers with comprised stomach capacity.</p>			

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1                   IMPROVED LIQUID NUTRITIONAL SUPPLEMENT AND  
2                   ASEPTIC PROCESS FOR MAKING SAME

3  
4                   Background Of The Invention

5  
6                  The present invention is directed to an improved nutritional supplement and process  
7                  for making same, and more particularly, to a liquid nutritional supplement which provides  
8                  improved concentration of many recommended macro- and micro-nutrients in a shelf-stable  
9                  form. The present invention is also directed to a process for improving the shelf-stability and  
10                 flavor profile of a liquid nutritional supplement, in which the supplement undergoes ultra-  
11                 high temperature (UHT) processing while flowing through the UHT processor in a turbulent  
12                 state and is then subjected to higher-pressure homogenization.

13  
14                 Currently, there are several liquid nutritional supplements available on the market,  
15                 which have found application in many areas, including as a meal supplement or a meal  
16                 replacement. The supplements contain enhanced levels of protein, fat, carbohydrate, vitamins  
17                 and minerals which may benefit the consumers of the supplements in accomplishing balanced  
18                 nutrition and thus maintain a good health. They are flavored and homogenized to improve  
19                 their appearance, flavor profiles and taste, which are important factors in consumer  
20                 acceptability and commercial success of the supplement. Supplements of this type include  
21                 ENSURE and PULMOCARE brands from Ross Laboratories, a division of Abbott  
22                 Laboratories, SUSTACAL and TRAUMACAL brands from Mead Johnson & Co., and  
23                 RESOURCE from Sandoz Ltd. These supplements generally have a total solids content  
24                 under 30% by total weight of the supplement, and thus have a large excess of water as  
25                 compared to the amount of water necessary to solubilize the components of the supplement.

26  
27                 Nutritional supplements on the market today are available in no less than 8 or 10  
28                 ounce sizes, and in order to obtain the full benefit of the dietary supplement it must be  
29                 entirely consumed. However, as a result of age-related and other factors, some people often  
30                 have an undersized stomach and reduced appetite, so that the total volume of liquid and solid  
31                 food which can be consumed is limited. An example of a patent directed to a higher-volume  
32                 dietary supplement is U.S. Patent No. 4,497,800 to Larsen et al.

33  
34                 In addition, the presence of high levels of nutrients, especially minerals, while  
35                 essential to the effectiveness of a nutritional supplement, has a counterproductive effect on  
36                 the solubility of the components of the supplement and the consistency of the resulting liquid.  
37                 In particular, the components can separate out into organic and aqueous phases, and minerals

1 can settle out of the liquid to form sedimentation on the bottom of the container during the  
2 expected shelf life of the packaged supplement. Such separation and sedimentation are  
3 undesirable for a number of reasons. One, it is visually unappealing to intended consumers  
4 of the supplement, and reduces the likelihood that the supplement will be fully consumed.  
5 Second, it reduces the efficacy of the supplement, if the minerals have settled out of the liquid  
6 being consumed and hardened into a nondispersible form.

7  
8       The liquid nutritional supplement must also be sterilized so that it will be  
9 "commercially sterile," or safe for human consumption during its expected shelf life.  
10 Conventionally, liquid nutritional supplements have been sterilized through the use of a post-  
11 packaging retorting process, in which a homogenized liquid mixture of nutrients is packaged  
12 in a hermetically sealed container and then the container is subjected to steam heating under  
13 pressure for an extended period of time equivalent to approximately 5-10 minutes at 121 °C.  
14 From the onset of steam-on to steam-off, this process could take 20-60 minutes to accomplish  
15 commercial sterility. This retorting process is abusive to the container itself as well as the  
16 heat-sensitive nutrients of liquid nutritional supplements, and may accelerate the process of  
17 separation and sedimentation discussed above. It also exerts an adverse effect on the aroma  
18 and taste of the final product. U.S. Patent No. 4,497,800 to Larsen et al. is one example of a  
19 supplement sterilized by this retorting process.

20  
21       Another method for sterilizing certain types of nutritional formulations is referred to  
22 as continuous thermal or UHT (ultra-high temperature) processing, also known as aseptic  
23 processing. UHT processing can be accomplished by direct injection of steam into the liquid  
24 to be sterilized, or by indirect heating of the liquid as it flows through a tube surrounded by  
25 steam or past a heat exchanger plate. The raw product is sterilized before being packaged in  
26 previously sterilized containers. In this aseptic process, the product mixture is subjected to  
27 brief but intense heating in the temperature range of 130-145 °C, for a time sufficient to  
28 commercially sterilize the product, approximately 2-45 seconds. The use of UHT processing  
29 to sterilize a certain kind of nutritional formulation having a high acidity and primarily using  
30 whey as the protein component of the nutritional supplement is discussed in U.S. Patent No.  
31 5,520,948 to Kvamme. The use of UHT processing in the preparation of a liquid nutritional  
32 supplement requiring the use of high proportion of a certain kind of stabilizer, iota-  
33 carrageenan, to maintain shelf stability is taught in U.S. Patent No. 5,416,077 to Hwang et al.

34  
35       The use of UHT processing is also known in the preparation of infant formula, dairy  
36 products, and non-dairy creamers, which all have much lower levels of nutrients than the  
37 nutritional supplements. Examples include U.S. Patent No. 4,748,028 to McKenna et al; U.S.

1 Patent No. 4,851,243, U.S. Patent No. 4,888,194, and U.S. Patent No. 4,9335,255, all to  
2 Anderson et al.; and U.S. Patent No. 5,378,488 to Dimler et al.

3  
4 The use of UHT processing in conventional low-acid liquid nutritional supplements  
5 using milk proteins such as caseinates as their protein source has encountered a number of  
6 difficulties. These difficulties are caused in part by the localized build-up of heat within the  
7 supplement during UHT processing. They are also caused in part by the high levels of micro-  
8 nutrient minerals present in the supplement, combined with the high levels of sources of  
9 protein and fat macro-nutrients. These difficulties include nonenzymatic browning, or "burn  
10 on", which causes an undesirable color and unpleasant flavor. In addition, fouling of the  
11 processing tubing has been encountered, caused by sedimentation and separation of the  
12 components during UHT sterilization. In an attempt to reduce the likelihood that minerals  
13 will separate out of the supplement during ultra high temperature processing, prior art  
14 supplements sterilized using this technique use if possible water-soluble compounds as  
15 sources of minerals. For example, ferrous sulfate is used as a source of iron.  
16

17 As a result of the presence of both hydrophobic and hydrophilic components in the  
18 liquid nutritional supplement, they are conventionally subjected to homogenization during  
19 processing. This improves the shelf stability as well as the flavor profile and appearance of  
20 the final liquid nutritional supplement. However, this homogenization is usually performed  
21 prior to UHT sterilization at pressures not exceeding 2,500 pounds per square inch (psi),  
22 based on experience gained in homogenization of dairy products.  
23

24 In light of the above, it would be desirable to provide a liquid nutritional supplement  
25 which provides improved concentration of many recommended macro- and micro-nutrients in  
26 a shelf-stable form. It would also be desirable to provide a fully aseptic sterilization and  
27 homogenization process for a liquid nutritional supplement resulting in improved shelf-  
28 stability and flavor profile.  
29

### 30 **SUMMARY OF THE INVENTION**

31 In accordance with the present invention, there is provided an improved liquid  
32 nutritional supplement which provides improved concentration of many recommended  
33 nutrients in a shelf-stable form. As used herein, a liquid nutritional product is "shelf-stable"  
34 if it is essentially devoid of separation or sedimentation over the expected shelf life of the  
35 product.  
36

37 The liquid nutritional supplement comprises:

1                             (a) a macro-nutrient component comprising 22 to 150 milligrams of protein  
2                             and 30 to 200 milligrams of fat per milliliter of supplement; and  
3                             (b) a mineral micro-nutrient component comprising 1.5 to 10 milligrams of  
4                             potassium; 0.4 to 2.97 milligrams of calcium; 0.17 to 1.18 milligrams of  
5                             magnesium; 0.42 to 2.97 milligrams of phosphorus; and 0.015 to 0.053  
6                             milligrams of iron per milliliter of supplement;

7                             wherein the nutritional supplement is commercially sterile and shelf-stable.

9                             In another aspect of the present invention, the commercially sterile and shelf-stable  
10                            liquid nutritional supplement comprises:

11                             (a) a macro-nutrient component comprising at least one source of protein, at  
12                             least one source of fat, and at least one source of carbohydrate,  
13                             (b) a mineral micro-nutrient component comprising at least one source of  
14                             mineral micro-nutrients which is virtually water-insoluble, and  
15                             (c) a stabilizer,

16                             wherein the total solids present in the supplement is not less than 30% of the total  
17                            weight of the supplement.

19                             In an additional aspect of the invention, the liquid nutritional supplement is sterilized  
20                            by continuous thermal processing at ultra-high temperature and comprises as a source of iron  
21                             ferric ortho-phosphate.

23                             One aspect of the invention is a process for maintaining emulsion stability and  
24                            extending the shelf life of a liquid nutritional supplement formulated as an emulsified slurry  
25                            comprising sources of macro-nutrients and then sterilized, comprising the step of passing the  
26                            emulsified slurry through a pump exerting a hydroshare of between 100 to 250 pounds per  
27                            square inch.

29                             In another aspect of the present invention, a process for aseptically sterilizing and  
30                            homogenizing a liquid nutritional supplement comprises the steps of:

31                             (a) heating the supplement to a temperature of at least 130 °C for a time  
32                             sufficient to commercially sterilize the supplement while the supplement is  
33                             passing through a hold tube under a pressure sufficient to keep the flow of the  
34                             supplement through the hold tube substantially turbulent;  
35                             (b) passing the supplement through a remote aseptic homogenizer having at  
36                             least one valve creating a pressure of at least 2,800 pounds per square inch

1                   wherein the valve also acts as a pressure restrictor on the supplement flow out  
2                   of the hold tube.

3  
4                   Yet another aspect of the invention is, in a processor for commercially sterilizing a  
5                   liquid having an entry point and an exit point for the liquid, a hold tube between the entry and  
6                   exit points, a chamber holding steam adjacent the hold tube for indirectly heating the liquid in  
7                   the hold tube to a temperature of at least 130 °C for a time sufficient to commercially sterilize  
8                   the supplement while the supplement is passing through the hold tube, and a means for  
9                   restricting the flow of the liquid out of the processor, the improvement which comprises:

10                  (a) increasing the thickness of the walls of the hold tube so that the hold tube  
11                  can withstand pressures up to 4,000 pounds per square inch;  
12                  (b) creating a continuous positive pressure through the system by the use of at  
13                  least one positive displacement pump controlled by a variable speed drive; and  
14                  (c) dynamically controlling the pump, the processor, and the means for  
15                  restricting the flow of the liquid out of the processor to ensure that the pressure  
16                  remains sufficiently high to keep the flow of the liquid through the hold tube  
17                  substantially turbulent.

18  
19                  A further aspect of the invention is, in a processor for commercially sterilizing a  
20                  liquid having a hold tube between the entry and exit points, and a chamber holding steam  
21                  adjacent the hold tube for indirectly heating the liquid in the hold tube to a temperature of at  
22                  least 130 °C for a time sufficient to commercially sterilize the supplement while the  
23                  supplement is passing through the hold tube, the improvement which comprises:

24                  maintaining a pressure on the liquid through the hold tube which is higher than  
25                  the pressure on the steam in the chamber adjacent the hold tube, such that if a  
26                  leak in the hold tube develops, no steam will enter the hold tube and  
27                  contaminate the sterile liquid in the hold tube.

28  
29                  DETAILED DESCRIPTION OF THE INVENTION

30                  The present invention is concerned with the formulation and manufacture of an  
31                  improved, commercially sterile liquid nutritional supplement. Thus, the description which  
32                  follows should be considered illustrative of a preferred embodiment and best mode for  
33                  practicing the invention, and not in any way a limit on the scope or applicability of the  
34                  various aspects of the invention herein.

35  
36                  In a preferred embodiment, the process for aseptically preparing and packaging the  
37                  improved liquid nutritional supplement of the present invention comprises (A) blending and

1 liquefying of ingredients to form an emulsion and (B) higher pressure sterilization by  
2 continuous thermal processing at ultra-high temperature followed by higher-pressure  
3 homogenization. The apparatus used to perform the various mechanical steps is any suitable  
4 equipment well-known to one skilled in the art, unless otherwise stated. This preferred  
5 process is discussed below.

6

7 **A. Blending and Liquefying of Ingredients**

8 One or more sources of proteins and one or more sources of carbohydrate are blended  
9 into a dry macro-nutrient mixture. Optionally, a stabilizer such as kappa-carrageenan and a  
10 wetting agent such as polysorbate 60 or 80 may be used. In a most preferred process, the  
11 protein is calcium sodium caseinates, and the carbohydrate is a fine sugar, which are used  
12 together with a stabilizer and a wetting agent in amounts as described below in Examples A  
13 and B. An alternative protein source is milk protein concentrate which has been subjected to  
14 ultrafiltration to reduce lactose. In a first mixing tank, this dry macro-nutrient mixture is then  
15 added to heated water and hydrated or solubilized into an aqueous formulation slurry.

16

17 Sources of minerals including potassium, calcium, magnesium, phosphorous and iron  
18 are blended into a dry mineral micro-nutrient mixture, and then mixed in water to form a  
19 mineral micro-nutrient slurry. This mineral micro-nutrient slurry is added to the aqueous  
20 formulation slurry. Most preferred sources and amounts of these minerals are described  
21 below in connection with Examples A and B.

22

23 Sources of trace minerals including iron, zinc, copper and iodine are blended into a  
24 dry trace mineral micro-nutrient mixture, and then mixed in water to form a trace mineral  
25 micro-nutrient slurry. A proper amount of the trace mineral micro-nutrient slurry is then  
26 added to the aqueous formulation slurry. Most preferred sources and amounts of these trace  
27 minerals are described below in connection with Examples A and B.

28

29 The pH of the nutrient slurry is then adjusted to about 6.9 to 7.0, or about 7.0 to 7.2 if  
30 an optional additional source of carbohydrate is added as discussed below. A source of fat is  
31 then added with agitation to form an emulsion with the aqueous nutrient slurry. The source  
32 of fat is most preferably one high in monounsaturated fatty acids, such as high oleic safflower  
33 oil, used in amounts as described below in connection with Examples A and B. Optionally,  
34 lecithin and vitamin E acetate can be added at this point to improve the emulsification and  
35 nutritional qualities of the supplement.

1       At this point, optionally an additional source of carbohydrate such as maltodextrin can  
2 be added to the emulsified slurry. Butter flavor, a vitamin premix of the type well known in  
3 the liquid nutritional supplement industry (such as those commercially available from  
4 Hoffman LaRoche, Inc., of Nutley, New Jersey, for example), sodium ascorbate and if  
5 desired chocolate flavor can be added to the emulsified slurry. The flavoring agents used  
6 herein may be any of a number of flavoring agents well known in the nutritional supplement  
7 industry (such as those commercially available from Universal Flavors, of Indianapolis,  
8 Indiana, for example). After agitation, the total solids of the emulsified slurry are adjusted by  
9 addition of water to not less than 30% of the total weight of the emulsified slurry. In the  
10 alternative embodiment including the addition of maltodextrin, the total solids are adjusted to  
11 not less than 38% of the total weight. Most preferred amounts of these ingredients are stated  
12 below in connection with Examples A and B.

13  
14       The solids-adjusted emulsified slurry is then passed through a tubular heat exchanger  
15 to a second mixing tank, passing through a pump exerting a hydroshear on the slurry of from  
16 between 100 to 250 psi. Alternatively, a homogenizer may be used in place of the hydroshear  
17 pump. However, without wishing to be bound by theory, it is believed that the use of a pump  
18 to hydroshear the emulsified slurry makes a more effective contribution than a homogenizer  
19 to the maintenance of an emulsion during overnight storage and deaeration. It is also  
20 believed that the use of a pump exerting a hydroshear to "deface" the supplement suspension  
21 may extend the shelf life and control gellation in the final liquid nutritional supplement  
22 product. In addition, a pump containing a hydroshear is easier to maintain and clean when  
23 necessary than a standard homogenizer.

24  
25       The slurry is then cooled and optionally flavored vanilla or strawberry to form the  
26 final supplement mixture. In addition, the cooled supplement mixture may be refrigerated at  
27 or below 7 °C and allowed to stand overnight (or at least 6 hours), which allows the  
28 supplement mixture to deaerate. Without wishing to be bound by theory, it is believed that  
29 this process of passing the emulsified slurry through a pump exerting a hydroshear and then  
30 allowing the supplement mixture to stand overnight results in a supplement with extended  
31 shelf life. Most preferred amounts of these ingredients and conditions of hydroshear and  
32 storage are stated below in connection with Examples A and B.

33  
34       The resulting nutritional supplement mixture is high in macro- and micro-nutrients,  
35 and provides about 1.7 calories per milliliter (cal/ml). If the optional additional source of  
36 carbohydrate is added, the supplement mixture provides about 2.0 cal/ml. Moreover, it is

1 much lower in sodium than liquid nutritional supplements not made according to the present  
2 invention, as illustrated below in the Comparative Nutrient Values chart.

3

4 **B. Higher Pressure Sterilization and Homogenization**

5 The cooled final supplement mixture is subjected to continuous thermal processing at  
6 ultra-high temperature (i.e., at a temperature of at least 130 °C) for a time sufficient to  
7 commercially sterilize the supplement while the supplement is passing through a hold tube  
8 under sufficient pressure to keep the flow of the supplement through the hold tube  
9 substantially turbulent. To achieve the sterilization required by applicable Food and Drug  
10 Administration regulations, the supplement mixture is exposed to temperature of about 140 to  
11 145 °C in the hold tube for about 2 to 45 seconds. In a most preferred process, the  
12 supplement is heated indirectly by steam while flowing through a spiral hold tube, the  
13 sterilization temperature is about 142 to 144 °C, and the total time in the hold tube at  
14 sterilization temperatures is 3 to 6 seconds. Alternatively, a straight or trombone-style tubing  
15 system can be employed. As exposure to sterilization temperature causes some destruction of  
16 the vitamins within the supplement mixture, the amount of vitamins added during  
17 formulation can be adjusted for longer or shorter sterilization times so as to result in the  
18 proper amount of vitamins in the final liquid nutritional supplement.

19

20 The UHT processing is performed using a Stork Sterideal Model 8000B indirect  
21 continuous thermal processor which has been specially modified to generate and then to  
22 withstand the pressure necessary to keep the flow through the processor substantially  
23 turbulent. First, the processor has been modified by use of high-pressure tubing having walls  
24 between 4.5 and 6 millimeters thick, and capable of withstanding pressures up to 4,000 psi.  
25 Second, the Stork processor has also been modified to provide for continuous positive  
26 pressure through the system by the use of one or more pumps having a variable speed drive  
27 and positive displacement to push the supplement into the UHT processor. Third, these  
28 pumps are dynamically controlled together with the modified Stork processor and a means  
29 for controlling the flow of the supplement out of the processor (most preferably the higher-  
30 pressure remote aseptic homogenizing valves (described below)) by the use of a computer to  
31 ensure that the pressure remains sufficiently high to keep the flow of the supplement through  
32 the hold tube substantially turbulent. In a most preferred process, the flow level is between  
33 2,000 and 8,000 liters per hour. By the use of these modifications, the pressure within the  
34 hold tube of the modified processor is not less than 2,800 psi, and the pressure drop through  
35 the modified processor in the most preferred process is not greater than 500 psi. The  
36 unmodified Stork Model 8000B is available from Stork Amsterdam of Amstelveen,  
37 Netherlands.

1  
2       The flow of the supplement through the tubing is considered "turbulent", as used  
3 herein, if it contains at least some internal flow patterns in directions non-parallel to the  
4 direction of flow of the supplement through the tubing. It is believed that this turbulent flow  
5 prevents the localized build-up of heat and allows the sterilization heat to disperse more  
6 evenly and rapidly throughout the supplement in the tube than non-turbulent, laminar flow.  
7 Thus, it is believed that the turbulent flow of the supplement during UHT processing  
8 contributes to the improved flavor profile and taste of the sterilized nutritional supplement,  
9 and also prevents heat-induced emulsion instability which could lead to fouling of the UHT  
10 processing system and shorten the expected shelf life of the packaged supplement.

11  
12      The supplement is then subjected to a remote (i.e., after sterilization) aseptic  
13 homogenizing valve creating a pressure of at least about 2,800 psi. Optionally, the  
14 supplement is then passed through a second homogenizing valve creating a pressure of about  
15 500 to 1,000 psi. In a most preferred process, the supplement is subjected to double-stage  
16 "downstream" (i.e., after sterilization) homogenization at a first stage valve pressure of  
17 approximately 3,100 psi, and a second stage valve pressure of about 500 psi. The first stage  
18 homogenization valve also acts as a pressure restrictor on the supplement flow out of the  
19 tubing of the modified Stork UHT processor, thereby (1) keeping the pressure within the hold  
20 tube sufficiently high so that the flow of the supplement is substantially turbulent and  
21 (2) eliminating the need for a separate "stuffer" pump to feed the supplement through the  
22 homogenizing valves. Without being bound by theory, it is believed that pressures above  
23 about 2,800 psi are more effective at homogenizing vegetable oils such as safflower oil,  
24 which are the sources of fat used in nutritional supplements, than conventional pressures of  
25 around 2,500 psi currently used in the nutritional supplement industry, which were designed  
26 based on experiences with dairy products having milk fats.

27  
28      As part of this higher pressure UHT processing, the supplement in the hold tube is at a  
29 higher pressure than the steam in a chamber adjacent the hold tube used to indirectly heat the  
30 supplement flowing through the hold tube to the sterilization temperature. Thus, if a small  
31 leak in the tubing develops, no steam will enter the hold tube and contaminate the sterile  
32 liquid in the hold tube. A small amount of supplement may escape into the adjacent steam,  
33 but this will not affect the sterility of the supplement remaining in the hold tube and exiting  
34 the processor. Moreover, because the pressure on the supplement increases as the supplement  
35 passes through the hold tube, the sterile supplement toward the end of the hold tube is at a  
36 higher pressure than the supplement which has just entered the processor. Upon entering the  
37 processor, this non-sterile supplement may pass through tubing adjacent to the tubing holding

1 the outgoing sterile supplement in order to receive heat from the outgoing sterile supplement.  
2 Thus, if a small leak develops in the tubing between the entering non-sterile supplement and  
3 the exiting sterile supplement, the sterile supplement will not be contaminated by non-sterile  
4 supplement. This ensures that the supplement remaining in the tube and exiting the processor  
5 will be sterile, in compliance with applicable U.S. Food and Drug Administration  
6 requirements, and thus will not need to be discarded.

7  
8 As a result of this higher-pressure homogenization, the product is thoroughly  
9 homogenized, resulting in reduction of droplet size as compared to liquid nutritional  
10 supplements homogenized at lower pressures. The higher-pressure sterilization and  
11 homogenization of the present invention leads to prolonged emulsion stability and expected  
12 shelf life, and to a liquid product having superior mouth feel and flavor.

13  
14 The following examples provide illustration of the invention but are not intended to  
15 limit the scope of the invention hereto. Examples A and B are liquid nutritional supplements  
16 formulated in accordance with most preferred embodiments of the instant invention.. To  
17 illustrate the improvement represented by the present invention, following Examples A and B  
18 is a chart comparing the macro- and mineral micro-nutrient values of four ounces (118 ml) of  
19 Example A with four ounces of two prior art supplements, TRAUMACAL available from  
20 Mead Johnson & Co., and PULMOCARE available from Ross Laboratories, a division of  
21 Abbot Laboratories, Inc.

22  
23 **Example A**

24 To form the dry macro-nutrient mixture, 805 pounds (lbs) of calcium sodium  
25 caseinate, 800 lbs of fine sugar, 2.6 lbs of polysorbate 80 and .84 lbs of kappa-carrageenan  
26 are blended together. This dry macro-nutrient mixture is then added to 5,500 lbs of water  
27 which has been pretreated through reverse osmosis and deionization, and heated to about 43 to  
28 54 °C. This aqueous formulation slurry is then blended for 15 minutes.

29  
30 To form the dry mineral micro-nutrient mixture, 32 lbs of dipotassium phosphate, 28  
31 lbs of potassium citrate, 34 lbs of magnesium chloride, 5 lbs of magnesium carbonate, 5 lbs  
32 of calcium phosphate (tribasic) and 6 lbs of calcium carbonate are added to 30 gallons of  
33 pretreated water to form the mineral micro-nutrient slurry. The entire volume of this mineral  
34 micro-nutrient slurry is then added to the aqueous formulation slurry.

35  
36 The inventors have found the use of magnesium carbonate as a source of magnesium  
37 to be particularly advantageous in the relatively concentrated liquid nutritional supplement of

1 the present invention, which has total solids of not less than 30% of the total weight of the  
2 supplement. This is because, as a virtually water-insoluble compound, magnesium carbonate  
3 does not tax the limited water available in the supplement. The inventors have found that the  
4 magnesium carbonate can be kept in suspension over the expected shelf life of the product by  
5 the use of a stabilizer, most preferably kappa-carrageenan. For the same reasons, the  
6 inventors have found the use of calcium carbonate, another virtually water-insoluble source  
7 of a mineral micro-nutrient, to be particularly advantageous. This source of calcium can also  
8 be kept in suspension by the use of a stabilizer which is most preferably kappa-carrageenan.  
9

10 To form the dry trace mineral micro-nutrient mixture, 544 grams (g) of ferric ortho-  
11 phosphate, 454 g of zinc sulfate, 95 g of copper gluconate and 1.4 g of potassium iodide are  
12 added to 1 gallon of pretreated water to form the trace mineral micro-nutrient slurry. The  
13 entire volume of this trace mineral micro-nutrient slurry is then added to the aqueous  
14 formulation slurry. The aqueous formulation slurry is then agitated and maintained at about  
15 43 to 54 °C to solubilize and fully hydrate, or to suspend, the macro- and micro-nutrients in  
16 the slurry.

17  
18 The inventors have found the use of ferric ortho-phosphate as a source of iron to be  
19 particularly advantageous for two reasons. One, it is virtually water-insoluble, and so does  
20 not tax the limited water available in the relatively concentrated liquid nutritional supplement  
21 of the present invention, as explained above. The inventors have found that it can be kept in  
22 suspension by the use of a stabilizer, most preferably kappa-carrageenan. Two, it does not  
23 cause discoloration of the liquid nutritional supplement during continuous thermal processing  
24 at ultra-high temperatures. The inventors have determined that the use of ferrous sulfate,  
25 which is commonly used in liquid nutritional supplements as a source of iron, causes the  
26 liquid nutritional supplement to turn gray during UHT processing. This discoloration makes  
27 the liquid nutritional supplement less appealing to the intended consumer and may require the  
28 use of strong colorings in order to mask the discoloration. Without wishing to be bound by  
29 theory, it is believed that the formation of iron sulfide during UHT processing causes this  
30 discoloration.

31  
32 Following the blending of the aqueous formulation slurry for 5 minutes, the pH is  
33 adjusted to 6.9 to 7.0 with 20% potassium hydroxide. Then 830 lbs of high oleic safflower  
34 oil, preheated to 93 °C are added to the aqueous formulation slurry. Vitamin E acetate in the  
35 amount of 0.6 lbs and lecithin in the amount of 32 lbs are dissolved in 50 lbs of safflower oil  
36 and added to the aqueous formulation slurry. The mixture is then agitated to further the  
37 emulsification and blending process for about 15 minutes. Butter flavor (2.5 lbs), and a

1       vitamin dry mixture of 4.6 lbs of vitamin premix and 3.2 lbs of sodium ascorbate are added to  
2       the emulsified slurry. The emulsified slurry is then blended for 5 minutes and the total solids  
3       are adjusted to 31.5 % of the total weight of the emulsified slurry.

4

5       The emulsified slurry is then passed through a Moyno type pump exerting a  
6       hydroshear between 195 to 205 psi at 150 gallons per minute and then cooled to about 22 °C.  
7       The cooled slurry is then flavored with 23 lbs of vanilla flavoring to form the final  
8       supplement mixture. The cooled supplement mixture is then refrigerated at 2-4 °C and  
9       allowed to stand overnight before being subjected to UHT sterilization and aseptically  
10      packaged.

11

12

### Example B

13       To form the dry macro-nutrient mixture, 480 pounds (lbs) of calcium/sodium  
14       caseinate, 550 lbs of fine sugar, 2.6 lbs of polysorbate 60 and 1.70 lbs of kappa-carrageenan  
15       are blended together. This dry macro-nutrient mixture is then added to 4,400 lbs of water  
16       which has been pretreated through reverse osmosis and deionization, and heated to about 43 to  
17       54 °C. This aqueous formulation slurry is then blended for 15 minutes.

18

19       To form the dry mineral micro-nutrient mixture, 15 lbs of dipotassium phosphate, 50  
20       lbs of potassium citrate, 23 lbs of magnesium chloride, 1.0 lbs of calcium phosphate (tribasic)  
21       and 20 lbs of calcium carbonate are added to 30 gallons of pretreated water to form the  
22       mineral micro-nutrient slurry. The entire volume of this mineral micro-nutrient slurry is then  
23       added to the aqueous formulation slurry.

24

25       To form the dry trace mineral micro-nutrient mixture, 272 grams (g) of ferric ortho-  
26       phosphate, 227 g of zinc sulfate, 50 g of copper gluconate and 0.68 g of potassium iodide are  
27       added to 1 gallon of pretreated water to form the trace mineral micro-nutrient slurry. The  
28       entire volume of this trace mineral micro-nutrient slurry is then added to the aqueous  
29       formulation slurry. The aqueous formulation slurry is then agitated and maintained at about  
30       43 to 54 °C to solubilize and fully hydrate, or to suspend, the macro- and micro-nutrients in  
31       the slurry.

32

33       Following the blending of the aqueous formulation slurry for 5 minutes, the pH is  
34       adjusted to 7.1 to 7.2 with 20% potassium hydroxide. Then 710 lbs of high oleic safflower  
35       oil, preheated to 93 °C are added to the aqueous formulation slurry. Vitamin E acetate in the  
36       amount of 1.0 lbs and lecithin in the amount of 20 lbs are dissolved in 50 lbs of safflower oil  
37       and added to the aqueous formulation slurry. The mixture is then agitated to further the

1 emulsification and blending process for about 15 minutes. Maltodextrin in the amount of  
2 1,550 lbs is then added. Butter flavor (6.7 lbs), and a vitamin dry mixture of 2.5 lbs of  
3 vitamin premix and 2.8 lbs of sodium ascorbate are added to the emulsified slurry. The  
4 emulsified slurry is then blended for 5 minutes and the total solids are adjusted to 38.5 % of  
5 the total weight of the emulsified slurry.

6  
7 The emulsified slurry is then passed through a Moyno type pump exerting a  
8 hydroshear between 195 to 205 psi at 150 gallons per minute and then cooled to about 22 °C.  
9 The cooled slurry is then flavored with 23 lbs of vanilla flavoring to form the final  
10 supplement mixture. The cooled supplement mixture is then refrigerated at 2-4 °C and  
11 allowed to stand overnight before being subjected to UHT sterilization and aseptically  
12 packaged.  
13

1

**Comparative Macro- and Mineral Micro-Nutrient Values\***

<b>Composition</b>	<b>Example A</b>		<b>TRAUMACAL</b>		<b>PULMOCARE</b>	
	<b>Amount</b>	<b>% Daily Value**</b>	<b>Amount</b>	<b>% Daily Value**</b>	<b>Amount</b>	<b>% Daily Value**</b>
Calories	200	***	178	***	178	**
Protein	10 g	20	9.8 g	19.5	7.4 g	17
Fat	13 g	20	8.1 g	12.5	11.05 g	4
Carbohydrate	11 g	4	17.0 g	5.5	12.5 g	4
Sodium	65 mg	3	140 mg	6.0	155 mg	6.5
Potassium	380 mg	10	165 mg	4.5	205 mg	6
Calcium	206 mg	20	88.5 mg	9.0	125 mg	12.5
Magnesium	82 mg	20	23.5 mg	6.0	50 mg	12.5
Phosphorus	210 mg	20	88.5 mg	9.0	125 mg	12.5
Iron	4.4 mg	20	1.05 mg	6.0	2.25 mg	12.5
Copper	0.42 mg	20	0.175 mg	9.0	0.25 mg	12.5
Zinc	3.2 mg	20	1.75 mg	12	2.8 mg	18
Iodine	33.0 mcg	20	8.85 mcg	6.0	18.75 mcg	12.5

2

3       \* The values for 4 fluid ounces of TRAUMACAL and PULMOCARE are calculated  
4       based on the label information given for 8 fluid ounces (236 ml) of those prior art  
5       supplements.

6       \*\* Percent Daily Values are based on a 2,000 calorie diet.

7       \*\*\* The U.S. Food and Drug Administration has not established % Daily Value.

8

9       Thus, an improved liquid nutritional supplement having improved flavor profile and  
10      taste which provides improved concentration of many recommended macro- and micro-  
11      nutrients in a shelf-stable form has been provided. One skilled in the art will appreciate that  
12      the present invention can be practiced by other than the described embodiments, which are  
13      presented here for purposes of illustration and not of limitation, and that the present invention  
14      is limited only by the claims that follow.

1       **WHAT IS CLAIMED:**

2       1. A liquid nutritional supplement comprising:

3               (a) a macro-nutrient component comprising 22 to 150 milligrams of protein  
4                   and 30 to 200 milligrams of fat per milliliter of supplement; and

5               (b) a mineral micro-nutrient component comprising 1.5 to 10 milligrams of  
6                   potassium; 0.4 to 2.97 milligrams of calcium; 0.17 to 1.18 milligrams of magnesium;  
7                   0.42 to 2.97 milligrams of phosphorus; and 0.015 to 0.053 milligrams of iron per  
8                   milliliter of supplement;

9                   wherein the nutritional supplement is commercially sterile and shelf-stable.

10       2. The liquid nutritional supplement of claim 1, wherein the macro-nutrient  
11           component further comprises 50 to 350 milligrams of carbohydrate and the total solids  
12           present in the supplement is not less than 30% of the total weight of the supplement.

13       3. The liquid nutritional supplement of claim 2, wherein:

14               (a) the macro-nutrient component comprises about 85 milligrams of  
15                   protein, about 110 milligrams of fat, and about 93 milligrams of carbohydrate per  
16                   milliliter of supplement; and

17               (b) the mineral micro-nutrient component comprises about 3.2 milligrams  
18                   of potassium; about 1.75 milligrams of calcium; about 0.69 milligrams of magnesium;  
19                   about 1.78 milligrams of phosphorus; and about 0.037 milligrams of iron per milliliter  
20                   of supplement.

21       4. The liquid nutritional supplement of claim 2, wherein:

22               (a) the macro-nutrient component comprises about 51 milligrams of  
23                   protein, about 93 milligrams of fat, and about 237 milligrams of carbohydrate per  
24                   milliliter of supplement; and

25               (b) the mineral micro-nutrient component comprises about 3.2 milligrams  
26                   of potassium; about 1.75 milligrams of calcium; about 0.34 milligrams of magnesium;  
27                   about 0.89 milligrams of phosphorus; and about .0195 milligrams of iron per milliliter  
28                   of supplement.

29       5. A commercially sterile and shelf-stable liquid nutritional supplement  
30           comprising

31               (a) a macro-nutrient component comprising at least one source of protein,  
32                   at least one source of fat, and at least one source of carbohydrate,

33               (b) a mineral micro-nutrient component comprising at least one source of  
34                   mineral micro-nutrients which is virtually water-insoluble, and

35               (c) a stabilizer,

1                   wherein the total solids present in the supplement is not less than 30% of the  
2                   total weight of the supplement.

3         6.       The liquid nutritional supplement of claim 5, wherein the virtually water-  
4                   insoluble source of mineral micro-nutrients is selected from the group consisting of  
5                   magnesium carbonate, ferric ortho-phosphate, and calcium carbonate.

6         7.       The liquid nutritional supplement of claim 5, wherein the supplement is  
7                   sterilized at least in part by continuous thermal processing at a temperature of at least 130 °C  
8                   for a time sufficient to commercially sterilize the supplement.

9         8.       The liquid nutritional supplement of claim 5 wherein a source of protein is  
10                  calcium sodium caseinates.

11         9.       The liquid nutritional supplement of claim 5 wherein a source of protein is  
12                  milk protein concentrate which has been subjected to ultrafiltration to reduce lactose.

13         10.      The liquid nutritional supplement of claim 5 wherein a source of fat is high in  
14                  monounsaturated fatty acids.

15         11.      The liquid nutritional supplement of claim 10 wherein a source of fat is high  
16                  oleic safflower oil.

17         12.      The liquid nutritional supplement of claim 5 wherein the source of  
18                  carbohydrate is fine sugar, and the pH is adjusted to about 6.9 to 7.0.

19         13.      The liquid nutritional supplement of claim 5 wherein a source of carbohydrate  
20                  is fine sugar, an additional source of carbohydrate is maltodextrin, the pH is adjusted to about  
21                  7.0 to 7.2, and the total solids are not less than 38% of the total weight of the supplement.

22         14.      The liquid nutritional supplement of claim 5 wherein the stabilizer is kappa-  
23                  carrageenan.

24         15.      The liquid nutritional supplement of claim 5 further comprising a wetting  
25                  agent.

26         16.      The liquid nutritional supplement of claim 15 wherein the wetting agent is  
27                  selected from the group consisting of polysorbate 60 and polysorbate 80.

28         17.      The liquid nutritional supplement of claim 5 wherein the mineral micro-  
29                  nutrient component comprises sources of potassium, calcium, magnesium, phosphorous and  
30                  iron.

31         18.      The liquid nutritional supplement of claim 17, wherein the mineral micro-  
32                  nutrient sources are selected from the group consisting of dipotassium phosphate, potassium

1 citrate, magnesium chloride, magnesium carbonate, calcium phosphate (tribasic) and calcium  
2 carbonate.

3 19. The liquid nutritional supplement of claim 5 further comprising a trace  
4 mineral micro-nutrient component comprising at least one source of iron, zinc, copper and  
5 iodine.

6 20. The liquid nutritional supplement of claim 19 wherein the sources of trace  
7 mineral micro-nutrients are ferric ortho-phosphate, zinc sulfate, copper gluconate, and  
8 potassium iodide.

9 21. The liquid nutritional supplement of claim 5 further comprising lecithin,  
10 vitamin E acetate, flavorings, vitamins and sodium ascorbate.

11 22. The liquid nutritional supplement of claim 5 wherein the supplement provides  
12 at least about 1.7 calories per milliliter.

13 23. The liquid nutritional supplement of claim 13 wherein the supplement  
14 provides at least about 2.0 calories per milliliter.

15 24. A liquid nutritional supplement sterilized by continuous thermal processing at  
16 ultra-high temperature comprising as a source of iron ferric ortho-phosphate.

17 25. A process for maintaining emulsion stability and extending the shelf life of a  
18 liquid nutritional supplement formulated as an emulsified slurry comprising sources of  
19 macro-nutrients and then sterilized, comprising the step of passing the emulsified slurry  
20 through a pump exerting a hydroshear of between 100 to 250 pounds per square inch.

21 26. The process of claim 25, further comprising the steps of  
22 (a) cooling the supplement to a temperature below about 7 °C and  
23 (b) allowing the supplement to stand for not less than 6 hours before sterilizing  
24 the supplement.

25 27. The process of claim 25 wherein the pump is exerting a hydroshear of between  
26 195 to 205 pounds per square inch.

27 28. A process for aseptically sterilizing and homogenizing a liquid nutritional  
28 supplement comprising the steps of:

29 (a) heating the supplement to a temperature of at least 130 °C for a time  
30 sufficient to commercially sterilize the supplement while the supplement is passing  
31 through a hold tube under a pressure sufficient to keep the flow of the supplement  
32 through the hold tube substantially turbulent;

(b) passing the supplement through a remote aseptic homogenizer having at least one valve creating a pressure of at least 2,800 pounds per square inch wherein the valve also acts as a pressure restrictor on the supplement flow out of the hold tube.

29. The process of claim 28, wherein the supplement is heated indirectly while flowing through a spiral heat tube.

30. The process of claim 29, wherein the supplement mixture is heated to a temperature of about 140 - 145 °C for about 2 to 45 seconds.

31. The process of claim 30, wherein the supplement mixture is heated to a temperature of about 142 - 144 °C for about 3 to 6 seconds.

32. The process of claim 28, wherein the supplement is passed through a second remote aseptic homogenizing valve creating a pressure of at least about 500 pounds per square inch.

33. The process of claim 32, wherein the supplement is passed through a double stage homogenizer having a first stage valve creating a pressure of 3,100 pounds per square inch and a second stage valve pressure creating a pressure of 500 pounds per square inch.

34. In a processor for commercially sterilizing a liquid having an entry point and an exit point for the liquid, a hold tube between the entry and exit points, a chamber holding steam adjacent the hold tube for indirectly heating the liquid in the hold tube to a temperature of at least 130 °C for a time sufficient to commercially sterilize the supplement while the supplement is passing through the hold tube, and a means for restricting the flow of the liquid out of the processor, the improvement which comprises:

(a) increasing the thickness of the walls of the hold tube so that the hold tube can withstand pressures up to 4,000 pounds per square inch;

(b) creating a continuous positive pressure through the system by the use of at least one positive displacement pump controlled by a variable speed drive; and

(c) dynamically controlling the pump, the processor, and the means for restricting the flow of the liquid out of the processor to ensure that the pressure remains sufficiently high to keep the flow of the liquid through the hold tube substantially turbulent.

35. The processor of claim 34, wherein the flow level of the liquid through the processor is between 2,000 and 8,000 liters per hour.

36. The processor of claim 34, wherein difference in pressure on the liquid at the entry point and the exit point is not more than 500 pounds per square inch.

1       37. The processor of claim 34, wherein the pressure within the hold tube is not  
2 less than 2,800 pounds per square inch.

3       38. In a processor for commercially sterilizing a liquid having a hold tube between  
4 the entry and exit points, and a chamber holding steam adjacent the hold tube for indirectly  
5 heating the liquid in the hold tube to a temperature of at least 130 °C for a time sufficient to  
6 commercially sterilize the supplement while the supplement is passing through the hold tube,  
7 the improvement which comprises:

8              maintaining a pressure on the liquid through the hold tube which is higher than  
9              the pressure on the steam in the chamber adjacent the hold tube, such that if a leak in  
10          the hold tube develops no steam will enter the hold tube and contaminate the liquid in  
11          the hold tube.

## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US97/21303

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :Please See Extra Sheet

US CL :Please See Extra Sheet

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 514/2, 8, 905; 426/72, 74, 590, 601, 656, 658; 366/136, 159, 160.2

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

APS, STN MEDICINE CLUSTER

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X ----	US 5,108,767 A (MULCHANDANI et al) 28 April 1992, Cols. 5-6, 1, 3-4, 9-10, 12-14, 19	1-2, 5-7, 9-13, 17, 19, 21-23, 28, 32 ----- 3-4, 8, 18, 24
X ----	US 5,340,603 A (NEYLAN et al) 23 August 1994, Cols. 9, 20-22. 1-6, 12-13	5-7, 10-11, 17, 19, 21 ----- 1-4, 14, 18, 20, 24
Y		

 Further documents are listed in the continuation of Box C. See patent family annex.

*A*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"B"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"L"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"O"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"A"	document member of the same patent family
"P"	document referring to an oral disclosure, use, exhibition or other means		
	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search

05 FEBRUARY 1998

Date of mailing of the international search report

26 FEB 1998

Name and mailing address of the ISA/US  
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## INTERNATIONAL SEARCH REPORT

International application No.

PCT/US97/21303

## C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X ---	US 5,545,411 A (CHANCELLOR) 13 August 1996, Cols. 1-6.	1-2, 5, 8-14, 17-19, 28, 32-33 -----
Y		3-4, 18, 25, 27
X ---	US 5,472,952 A (SMIDT, et al) 05 December 1995, Cols. 8-9.	1-2, 5, 10-11, 17, 19 -----
Y		3-4, 6, 8, 18, 20
X ---	US 5,520,948 A (KVAMME) 28 May 1996, Cols. 1-4. 8-9, 11-12	5, 8, 10-11, 17, 19 -----
Y		28, 32
Y	US 4,419,369 A (NICHOLS et al) 06 December 1983, Col. 3, lines 16-18.	8
Y	GB-1135552 A (PFIZER & CO INC) 31 August 1993, Abstract.	6, 20, 24
A	US 4,591,463 (NAHRA, et al) 27 May 1986, Entire Document	34-38
A	US 4,844,620 A (LISSANT, et al) 04 July 1989, Entire Document	34-38
A	US 5,378,488 A (DIMLER et al) 03 January 1995, Cols. 1-4.	34-38
A,P	US 5,656,317 A (SMITS et al) 12 August 1997, Entire Document	34-38

**INTERNATIONAL SEARCH REPORT**

International application No.

PCT/US97/21303

**Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)**

This international report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1.  Claims Nos.:  
because they relate to subject matter not required to be searched by this Authority, namely:
  
2.  Claims Nos.:  
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
  
3.  Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

**Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)**

This International Searching Authority found multiple inventions in this international application, as follows:

Please See Extra Sheet.

1.  As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2.  As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3.  As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
  
4.  No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

**Remark on Protest**  

The additional search fees were accompanied by the applicant's protest.

No protest accompanied the payment of additional search fees.

**INTERNATIONAL SEARCH REPORT**

International application No. PCT/US97/21303
---

**A. CLASSIFICATION OF SUBJECT MATTER:**

IPC (6):

A01N 37/18; A61K 38/00, 38/16; A23D 7/00, 9/00; A23G 3/00; A23J 1/00; A23L 1/30, 2/00; A23K 1/175; B01F 15/02; G05D 11/00

**A. CLASSIFICATION OF SUBJECT MATTER:**

US CL :

514/2, 8, 905; 426/72, 74, 590, 601, 656, 658; 366/136, 159, 160.2

**BOX II. OBSERVATIONS WHERE UNITY OF INVENTION WAS LACKING**

This ISA found multiple inventions as follows:

This application contains the following inventions or groups of inventions which are not so linked as to form a single inventive concept under PCT Rule 13.1. In order for all inventions to be searched, the appropriate additional search fees must be paid.

## Group

I, claim(s)1-24, drawn to a liquid nutritional supplement.

Group II, claim(s) 26-33, drawn to a process for maintaining emulsion stability and extending shelf life.

Group III, claim(s) 34-38, drawn to an improvement in a processor for commercially sterilizing a liquid.

The inventions listed as Groups I, II, and III do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the composition is its own distinct invention and the special technical feature of the composition is not required by Groups II and III. Additionally, the claimed apparatus, Group III is not specially adapted for the process of Group II.

The base claim of group II mentions a liquid nutritional supplement but it does not have to be the same liquid nutritional supplement claimed. This emulsification process could be applied to nutritional supplements other than those claimed by applicants, infant formula, dairy products and non-dairy creamers.

The apparatus of Group III does not have to be used in the process of Group II. Group II specifically deals with nutritional supplements while Group III is any liquid.